

## **EXHIBIT 1**

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	11/400,497		ALLAWAY ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Bao Qun Li		1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 May 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 49, 53 and 55-58 is/are pending in the application.
- 4a) Of the above claim(s) 56-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 49, 53 and 55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>May 25, 2007</u>  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

This is a response to the amendment filed on 05/25/07. Claims 49, 53, 55-58 have been amended. Claims 1-48, 50-52 and 54 have been canceled. Claims 49, 53 and 55-58 are pending. Claims 56-58 were withdrawn from consideration. Claims 49, 53 and 55 are considered before the examiner.

### ***Priority***

1. The priority of claims 49, 53 and 55 based on the provisional Application SN. 60,019,941 filing date on are still denied because the particular extracellular domain of CCR5 responsible for the fusion between HIV Monotropic envelop protein and the target cells bearing CD4 and CCR5 is not disclosed in the provision application 06/019,941, filed on June 14, 1996. Therefore, the priority of claims 53-55 are still considered to the filing date of **June 13, 1997**, unless Applicants can provide the detail support for the amended claims 49, 53 and 55.

### ***Claim Rejections - 35 USC § 101***

2. The rejection of claims 49-54 under **35 USC § 101** has been withdrawn in view of Applicants' amendment.

### ***Claim Rejections - 35 USC § 102***

3. The rejection of claim 49 under 35 U.S.C. 102(b) as being anticipated by Loetscher et al. (J. Biological Chem. 1994, Vol. 269, No. 7, pp. 232-237) has been withdrawn necessitated by Applicants amendment.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States:

5. Claims 49 and 53 are still rejected under 35 U.S.C. 102(b) as being anticipated by Samson et al. (Biochemistry, March 1996, Vol. 35, pp. 3362-3367).

6. Applicants traverse the rejection and submit that the claimed polypeptide is not the polypeptide with 352 consecutive amino acids as the one disclosed in Samson et al. The claimed polypeptide is a polypeptide consisting essential of the consecutive amino acids corresponding to a sequence presently in an extracellular domain of human CCR5 receptor, which includes the sequence set forth in SEQ ID NO: 7 that inhibits fusion property of HIV-1 to CD4+ cell, but it does not encompass the entire CCR5 with 352 amino acids. Applicants further argue that the Samson et al do not teach any particular fragment of the 352 amino acid sequence.

7. Applicants' argument has been respectfully considered; however, Applicant's arguments do not comply with 37 CFR 1.111(c) and are not persuasive to withdraw the rejection. Because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections. In the instant case, the amendment "consisting essential of" is still considered to be an open language that fails to limit the claimed polypeptide being less than 352 amino acid residues long or being any particular fragment of the CCR5. Therefore, claims 49 and 53 are still read on an isolated polypeptide comprising amino acid residues set forth in SEQ ID NO: 7 or polypeptide comprising a fragment having a property responsible for the fusion characteristic of CCR5 with HIV monotropic envelope protein. It does not limit that the claimed polypeptide is not the polypeptide encoding the entire CCR5 coding sequence. To this context, the CCR5 polypeptide taught by Samson et al. that comprises the sequence of SEQ ID NO: 7 and has a characteristic fragment responsible for the fusion activity, it therefore, still anticipates the claims. The rejection is maintained.

8. Claims 49 and 53 are still rejected under 35 U.S.C. 102(b) as being anticipated by Raport et al. submitted to NCBI AAC50598 on April 12, 1996. The polypeptide taught by Raport et al. in NCBI as CCR5 is further substantiated as evidenced by their publication on Raport et al. (J. B. C, July 1996, Vol. 271, No. 20, pp. 17161-17166).

Art Unit: 1648

9. Applicants argue that although the sequence taught by Raport et al. is not available until July 25, 1996, which is later than the priority date of the provision application 06/019,941, filed on June 14, 1996. Therefore, it cannot be considered as a prior art.

10. Applicants' argument has been respectfully considered. However, it is not fund persuasive because the priority of the current claims 49 and 53 are considered to be July 13, 1997. The cited reference is still considered as prior art that anticipates the claims.

11. The rejection of claim 49 under 35 U.S.C. 102(a) as being anticipated by Feng Y. et al. (Science 1996, 272(5263): 872-7) has been with drawn in view of Applicants' amendment.

***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

13. Claims 49, 53 and 55 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,025,154 A, 6,800,729B2, 6,511,826B2, or 6,265,184B1.

14. Applicants traverse the rejections and submit that the claimed polypeptide is not polypeptide with 352 consecutive amino acids as disclosed in the cited references. The claimed polypeptide is a polypeptide consisting essential of consecutive amino acids corresponding to a sequence presently in an extracellular domain of human CCR5 receptor, which includes the

Art Unit: 1648

sequence set forth in SEQ ID NO: 7 that is responsible for the fusion property of HIV-1 monotropic envelope protein with CD4/CCR5 positive cells, but it does not encompass the entire 352 amino acids of the CCR5.

15. Applicants' argument has been respectfully considered; however, Applicant's arguments do not comply with 37 CFR 1.111(c) and are not persuasive to withdraw the rejection. Because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections. In the instant case, the amendment "consisting essential of" is still considered to be an open language that fails to limit the claimed polypeptide being less than 352 amino acids long or being any particular fragment of the CCR5. Therefore, claims 49 and 53 are still read on an isolated polypeptide comprising an amino acid residues set forth in SEQ ID NO: 7 or polypeptide comprising a fragment having a property responsible for the fusion characteristic of CCR5. To this context, the CCR5 polypeptide taught by all cited references comprises the sequence of SEQ ID NO: 7 as well as the characteristic fragment responsible for the fusion activity of CCR5 polypeptide. The cited references therefore, still anticipate the claims. The rejections are maintained.

16. Claims 49, 53 and 55 are still rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,448,375B1.

17. Applicants traverse the rejection and submit that the 102(e) date of the cited reference "375B1" is March 03, 1997, which does not precede the priority date of the currently pending claims, i.e. June 14, 1996. Accordingly, US Patent No. 6,448,375B1 is not a proper 102 (e) reference.

18. Applicants' argument has been fully considered; however, it is not found persuasive because the priority of claims 49, 53 and 55 are still considered to be June 13, 1997. US Patent No. 6,448,375B1 still anticipates claims 49, 53, and 55. Rejection is maintained.

#### ***Claim Rejections - 35 USC § 112***

19. The rejection of claims 49, 53, and 55 under 35 U.S.C. 112, first paragraph has been withdrawn necessitated by applicants' amendment.

*Conclusion*

No claims are allowed.

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bao Qun Li

August 21, 2007

  
BRUCE R. CAMPPELL, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600



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11/400,497	04/07/2006	Graham P. Allaway	51320-AAA/JPW/AG	3119
23432 7590 09/12/2007 COOPER & DUNHAM, LLP 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036			EXAMINER LI, BAO Q	
			ART UNIT 1648	PAPER NUMBER
			MAIL DATE 09/12/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.